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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/787,170
Filing Date: February 27, 2004
Appellant(s): FOUERE ET AL.

Robert W. Mueller
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 8 June 2007 appealing from the Office action mailed 19 May 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

Examiner notes the submission of a substitute specification on 8 June 2007. Examiner has reviewed the originally filed specification (filed 27 February 2004), certified translation (filed 21 June 2004), preliminary amendment (filed 21 June 2004), and substitute specification (filed 8 June 2007), and has found all the disclosures in the substitute specification to be fully enabled by the certified translation. Accordingly, the substitute specification has been entered by the Examiner.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,629,533	Webb et al	10-2003
4,915,684	MacKeen et al	04-1990
3,949,750	Freeman	04-1976
5,163,959	Herrick	11-1992
4,959,048	Seder et al	09-1990

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the Appellant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-9, 11, & 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Webb et al. (6,629,533). Webb et al. disclose a punctum plug and method for inserting the punctum plug in the lachrymal duct using an insertion tool. The punctum plug (110/210/310/410/510) has a body or shaft that is substantially cylindrical with an axial bore therethrough for the passage of an insertion tool, and one or more flexible anchoring arms or elements attached to the external wall of the plug (see column 4, lines 7-45). The anchoring arms are constructed of a resilient material and are flexible enough to fold during the insertion procedure and then straighten out once in place. The anchoring arms function to retain the plug in the patient's punctum. As is shown in the figures, the anchoring arms may be in the shape of radial arms (or pins) and may be of the same length, different lengths, or varying lengths. The plug may have one or more disks. It is the position of the Examiner that the anchoring arms disclosed by Webb are equivalent to, or correspond to, Appellant's claimed pins, since the arms extend radially outward from the body in a helical formation, are of a constant length,

and serve to reinforce & stabilize the apparatus within the punctum. The shape is seen to be in the form of a cone (see figures 2-7). The apparatus is made of flexible material. Webb et al. discloses a method of inserting the plug into the punctum using an insertion tool.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Appellant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 15, & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. ('533) in view of MacKeen et al. (4,915,684). Webb et al. discloses the invention substantially as claimed, see rejection of claim 1 above, but fails to disclose

specifically that the punctum plug has an axial duct for the passage of tears and that the insertion tool used for inserting the plug is a push rod.

MacKeen et al. discloses a punctum plug and a method for inserting the plug. The plug comprises a body that is substantially cylindrical and has an axial bore or duct for the passage of tears. MacKeen et al. teaches that an insertion tool that is a dilating rod (i.e. push rod) is used to insert the plug into the punctum (see figures 5A-E). At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the plug of Webb et al. to include an open axial duct as taught by MacKeen et al. to meter the passage of lacrimal fluid (or tears) away from the eye, through the punctum while the plug was inserted.

Claims 12 & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. ('533) in view of Freeman (3,949,750). Webb et al. discloses the invention substantially as claimed, see rejection of claim 1 above, however, fails to disclose specifically that the insert is made of metal or shape memory metal. Freeman discloses a punctum plug that may be made of stainless steel or other inert metal material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implant of Webb et al. to be made of either stainless steel as taught by Freeman or to be made of or Nitinol (shape memory material), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07. Freeman discloses the use of metal for punctum plugs and it is

well known in the art to use shape memory metals such as Nitinol, since both are well received by the body.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. ('533) in view of Herrick (5,163,959). Webb et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the insert is made of a radio-opaque material that is visible with X-rays. Herrick discloses a canalicular implant that may be made of a material that is responsive to X-rays to aid in determining if the implant is properly located within the canaliculi during implantation (col. 13, lines 46-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implant of Webb et al. to be made of a material that is responsive to X-rays as taught by Herrick, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07.

Claims 16, 17, 22, & 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. ('533) in view of Seder et al. (4,959,048). Webb et al. discloses the invention substantially as claimed, see rejection of claim 1 above, however, fails to disclose specifically that the tool used to implant the plug includes jaws. Seder et al. discloses a lacrimal duct occluder and forceps for insertion of the occluder. A forceps is considered to have jaws. It would have been an obvious matter

of design choice to modify the method of insertion of Webb et al. to substitute the forceps as the tool, as taught by Seder et al., since Appellant has not disclosed that using a forceps device solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well.

(10) Response to Argument

With regard to claims 1 and 19, Appellant argues that the Webb disclosure does not disclose a lacrimal duct occluder with anchor arms that are "structured and arranged to straighten out when positioned to maintain the plug in position" as recited in claim 1. The Examiner respectfully disagrees. Webb illustrates a lacrimal implant that comprises arms in a straight position when unstressed (see FIG 2b). Webb further discloses that the implant is made from a resilient biocompatible material (see column 2, lines 42-43) and that the anchoring arms serve to retain the occluder in position when the punctual opening returns to its predilated size (see column 3, lines 27-30). Webb's disclosure of a resilient material (one that exhibits resilience, the capability of a body to recover its size and shape after deformation, see Merriam-Webster's Collegiate Dictionary, 10th Ed., 2001) indicates that the arms are, in fact, structured and arranged to straighten out, or return to their unstressed position as illustrated in FIG 2b, retaining the implant in place. Accordingly, the Webb disclosure meets the limitations of the claims.

Appellant argues that the Examiner's assertion that the anchoring arms disclosed by Webb are equivalent to the instantly claimed radial pins is an improper assertion for a 35 USC 102 rejection. Examiner respectfully submits that the rejection is not based on

the principle of substituting equivalent elements for one another. Examiner simply used the term "equivalent" to mean "corresponding to" and has clarified the rejection accordingly. It is the position of the Examiner that the anchoring arms disclosed by Webb correspond to the radial pins claimed by Appellant, meeting the limitations of the claims.

With regard to claims 10, 15, and 21, Appellant argues that there is no motivation to modify the Webb reference with the MacKeen reference, since the Webb reference does not disclose the use of a tool for insertion of the implant. However, Examiner notes that Webb specifically discloses that the disclosed implant may be inserted with the aid of an insertion tool (see column 4, lines 15-20). Webb reasonably suggests to one of ordinary skill in the art the step of using a tool to insert the implant. MacKeen teaches that an insertion tool that is a dilating rod (i.e. push rod) is used to insert the plug into the punctum (see figures 5A-E). Accordingly, all of the parts of the instantly claimed invention are known in the prior art. The only difference is the use of the Webb implant with the insertion tool disclosed by MacKeen. As a combination, the elements would have performed in the same manner as when used separately, and one of ordinary skill in the art would be motivated to make such a combination via known techniques to arrive at the combined device, producing predictable results. Together, the disclosures suggest using a tool to insert a lachrymal implant, and reasonably suggest the use of a push rod to one having ordinary skill in the art in order to dilate the punctum and insert the plug with a single instrument (see MacKeen column 6, line 63 to column 7, line 15). Therefore, it would have been obvious to one having ordinary skill in the art to use the

tool disclosed by MacKeen to insert the device disclosed by Webb, since the disclosures provide all the claim elements, which may be combined by conventional methods to produce predictable results.

With regard to claims 12 and 13, Appellant argues that Freeman fails to disclose that any portions of the disclosed metal implant are flexible. Examiner respectfully notes that Freeman discloses that the implant may be constructed of a Teflon polytretrafluoroethylene polymer material (see column 4, lines 44-55), which may be constructed to be flexible in some instances (see column 5, lines 24-26). It follows from the combination of those disclosures that the Freeman disclosure contemplates the use of a flexible or resilient material for the implant, which may be constructed of a metal. It is well-known in the art of surgical implants that Nitinol is an implantable metal with a shape memory, making it suitable for use as a lacrimal implant. It is the position of the Examiner that Webb teaches the claimed resilient implant, Freeman teaches the use of metal to construct the implant, and the substitution of a flexible metal known in the art for the metal disclosed by Freeman would yield only predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to substitute a shape memory metal as suggested by Freeman for the resilient material disclosed by Webb, since such a combination would have yielded predictable results to one of ordinary skill in the art.

With regard to claim 14, Appellant argues that the implants disclosed by Webb and Herrick are designed for deployment in different portions of the eye, and are therefore not properly combined. Examiner respectfully disagrees. In response to

Appellant's argument that the references comprise nonanalogous art, it has been held that a prior art reference must either be in the field of Appellant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the Appellant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Both the Webb device and the Herrick device are designed for implantation in the punctum to treat a patient with a tear deficiency, which is the same problem addressed by Appellant (see Webb column 1, lines 19-30, column 2, lines 20-33, Herrick column 1, lines 39-50). Accordingly, the references are directed to solving the same problem and are reasonably pertinent to the particular problem with which the Appellant was concerned, and are properly combined.

With regard to claims 16, 17, 22, and 23, Appellant argues that the Webb reference discloses no special tool for insertion, providing no motivation to use the forceps disclosed by Seder to insert a lacrimal implant. . However, Examiner notes that Webb specifically discloses that the disclosed implant may be inserted with the aid of an insertion tool (see column 4, lines 15-20). Webb reasonably suggests to one of ordinary skill in the art the step of using a tool to insert the implant. Seder et al. discloses a lacrimal duct occluder and forceps (which comprise jaws) for insertion of the occluder. Accordingly, all of the parts of the instantly claimed invention are known in the prior art. The only difference is the use of the Webb implant with the insertion tool disclosed by Seder. As a combination, the elements would have performed in the same manner as when used separately, and one of ordinary skill in the art would be motivated to make

such a combination via known techniques to arrive at the combined device, producing predictable results. Together, the disclosures suggest using a tool to insert a lachrymal implant, and reasonably suggest the use of an insertion tool with jaws to one having ordinary skill in the art in order to insert the plug without the need for specialized insertion tools (see Seder column 3, lines 5-15). Therefore, it would have been obvious to one having ordinary skill in the art to use the forceps disclosed by Seder to insert the device disclosed by Webb, since the disclosures provide all the claim elements, which may be combined by conventional methods to produce predictable results.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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